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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/917,385	07/27/2001	Lisa A.G. Tweardy	1461-R-00	9974

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IP Department
Schnader Harrison Segal & Lewis
1600 Market Street, 36th Floor
Philadelphia, PA 19103

EXAMINER

PHANIJPHAND, GWEN G

ART UNIT	PAPER NUMBER
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3731

DATE MAILED: 06/12/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/917,385

Applicant(s)

TWEARDY, LISA A.G. Ch

Examiner

Gwen Phanijphand

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 July 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 7/27/2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|----------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

Detailed Action

Drawing

The drawings are objected to because of the following informalities. On page 5 of the specification, lines 13 to 14 state that, "referring now to Figure 1, one embodiment of the present invention is shown as skull pin 10 which comprises a pin body 12 and pin tip 14", but Figure 1 is missing pin tip 14. On page 7 of the specification, line 18 states that the "radius of rounded end 38 is between 0.025 and 0.075 mm", but the drawing is missing "rounded end 38." On page 8 of the specification, lines 18 to 19 state, "Another embodiment of the ceramic tip of the present invention is shown in Figure 4", but the drawings lack a Figure 4.

Appropriate correction is required.

Claim Rejections – 35 U.S.C. 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 3, 4, 6, 7, and 8 are rejected under U.S.C. 102(b) as being anticipated by Bremer, U.S. Patent No. 4,612,930. Regarding claim 1, Bremer discloses in Figure 3 a skull pin, comprising a pin body and a pin tip formed from the insulator "crystal alumina ceramic material" (column 1, line 53), which protrudes from the proximal end of the pin body.

Regarding claim 2, Bremer states in column 1, lines 50-51, "a skull pin...includes a skull engaging portion which terminates in a pointed tip, and is of ceramic material."

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Regarding claim 3, Bremer states in column1, lines 50-51, "a skull pin...includes a skull engaging portion which terminates in a pointed tip, and is of ceramic material." This skull pin is used during imaging procedures and serves as an electrical insulator.

Regarding claim 4, Bremer displays in Figure 3 a pin body (27) that includes a bore (29) for receiving said pin tip (37).

Regarding claim 6, Bremer displays in Figure 3 a pin tip that includes a tapered end (36) having an angle between 30° and 50°.

Regarding claim 7, Bremer discloses a kit comprising of a halo (Figure1) and a skull pin (Figure 3, 25) wherein the pin comprises of a body (27) and an insert (37) formed from an insulating material ("ceramic": column1, lines 50-51), protruding from the distal end of said pin body. Bremer's insert is used for fixating the head and aid in imaging.

Regarding dependent claim 8, Bremer discloses in column 1, lines 50-51 a skull pin, which has an insert formed from the insulating material, ceramic.

Claim Rejections – 35 U.S.C. 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 5, 9, and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bremer, U.S. Patent No. 4,612,930.

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Regarding claim 5, Bremer shows a skull pin that is basically the same as that recited in claim 1 except that it has a pin body with a bore for receiving the pin tip as opposed to the pin tip with a bore for receiving the pin body as stated in claim 5. The reversal of the pin tip with a bore for receiving the pin body and pin body with a bore for receiving the pin tip is an obvious reversal of parts. It would have been obvious to one having ordinary skill in the art at the time the invention was made to use a pin tip with a bore for receiving the pin body interchangeably with a pin body with a bore for receiving the pin tip, since it has been held that a mere reversal of essential working parts of a device involves only routine skill in the art.

Claims 9 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bremer, U.S. Patent No. 4,612,930, in view of, Birk et al., U.S. Patent No. 5,961,528. Bremer shows a skull pin wherein the skull pin comprises a pin body and an insert formed from ceramic, an insulating material, protruding from a distal end of the pin body, but Bremer, however, lacks a kit comprising of skull tongs. Birk et al. disclose a skull pin similar to that of Bremer and also include skull tongs (12) as depicted in Figure 2. Skull tongs are useful for supporting the pins on both sides of the head. Bremer states that, "The skull pin may be used with a conventional halo...or with other skull fixation apparatus used in medical treatment or operative procedures (column 1, lines 25-28)." Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the kit of Bremer to include skull tongs since tongs and halos are known alternate and analogous devices, aiding in supporting the skull pins in equidistance between the skull and the fixation device around the head.

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Conclusion

The Prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Bremer, U.S. Patent No. 5,122,132 discloses a skull pin composed of ceramic, an electrical insulator and is used with a halo or concentric traction ring, which are analogous to tongs. Abboudi, U.S. Patent No. 5,849,012 discloses a clamping assembly constructed of two ceramic plates. D'Urso, U.S. Patent No. 5,752,962, displays in Figure 1 a surgical procedure including a head clamping device, analogous to skull tongs. Schlondorff et al., U.S. Patent No. 5,494,034 and Vilmeier, U.S. Patent No. 5,769,861 both provide a method of localizing an instrument using three dimensional information. Mata, U.S. Patent No. 6,342,054 displays a device for positioning pins and locking rods composed partly of ceramic.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gwen Phanijsphand whose telephone number is 703-305-4845. The examiner can normally be reached on Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Milano can be reached on 703-308-2496. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3590 for regular communications and 703-305-3590 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

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GP

May 22, 2002

Gwen Phanijphand
Patent Examiner
Art Unit 3731

A handwritten signature in black ink, appearing to read "Michael J. Milano", written over the printed name.

Michael J. Milano
Supervisory Patent Examiner
Technology Center 3700